

**ATTACHMENT 7 - 510(k) Summary**

JUN 18 1996

**1. Applicant's Name and Address**

Straumann USA (on behalf of Institut Straumann AG)  
One Alewife Center, Cambridge, MA 02140-2317  
Telephone Number: 617-868-3800  
Fax Number: 617-868-9111  
Contact Person: Ms. Carolyn M. Bitetti, Director, Regulatory Affairs  
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**2. Name of the Device**

Trade Name: ITI Esthetic Healing Caps  
Common Name: Healing cap or healing abutment  
Classification Name: Accessory to a dental implant (21 CFR 872.3640)

**3. Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)**

1. ITI Large Closure Screw
2. Brånemark Healing Abutments
3. Steri-Oss Healing Abutments
4. Implant Innovations' Healing Abutments

**4. Description of the Device**

The ITI esthetic healing caps are titanium devices which are mounted onto an ITI implant before the soft tissue is sutured in place around the implant. These healing caps are intended to protect the inner configuration of the ITI implant and the 45° outer shoulder of the implant during the healing phase after the placement of the implant. The esthetic healing caps also serve to maintain, form, and stabilize the soft tissue during the healing phase. The primary indication for the esthetic healing caps is in the esthetic zone of the oral cavity where soft tissue conditioning is essential to achieve an optimal esthetic result with implant-borne restorations. The esthetic healing cap remains in place for six to twelve weeks.

The ITI esthetic healing cap is available in two heights (2.0 mm and 3.5 mm). Each cap consists of two parts: the body of the healing cap itself and a corresponding occlusal screw which affixes the cap onto the implant. The healing caps and the occlusal screws are composed of commercially pure Grade 4 titanium meeting ASTM F67-95.

The esthetic healing caps are designed with a bevel which should be positioned either labially or buccally. This bevel enables positioning of the mucoperiosteal flap over the esthetic healing cap after implant placement without subjecting the flap to tension.

5. **Intended Use of the Device**

The esthetic healing caps are intended to protect the inner configuration of the ITI implant and the outer 45° shoulder of the implant during the healing phase after implant placement. The esthetic healing cap also serves to maintain, form, and stabilize the soft tissue during the healing phase. The primary indication for the esthetic healing cap is in the intra-oral esthetic zone where soft tissue conditioning is essential to achieve optimal esthetic results with implant-borne restorations.

6. **Summary of Technological Characteristics of Device Compared to Predicate Devices**

Feature		Predicate Devices			
		ITI Large Closure Screw	Brånemark Healing Abutments	Implant Innovations Healing Abutments	Steri-Oss Healing Abutments
<b><i>Intended Use</i></b>					
To form, stabilize, and maintain the soft tissue.		YES	YES	YES	YES
<b><i>Material</i></b>					
Titanium		YES	YES	YES	YES
<b><i>Design</i></b>					
Diameters (mm)		6.0 mm	5.0 mm	4.5 mm - 7.5 mm	3.5 mm - 6.0 mm
Heights (mm)		1.5 mm	3.0 mm - 7.0 mm	2.0 mm - 8.0 mm	5.0 mm - 7.0 mm
Inserted directly into the implant during soft tissue healing period.		YES	YES	YES	YES